From: Betty Donoval, JD, MS  
    Director, Research Regulatory Affairs  
To: Sponsors  
Re: Compliance 2022  

The Cook County Health Institutional Review Board (IORG0000119 expiration 9/4/2023) is included in the System’s Federal Wide Assurance (FWA00001802 expiration 11/24/2026).

The IRB reviews human subject research protocols for all System affiliates:
    John H. Stroger Hospital of Cook County  
    Provident Hospital  
    Oak Forest Health Center of Cook County  
    Ambulatory and Community Health Network  
    Ruth Rothstein CORE Center  
    Cermak Health Services  
    Cook County Department of Public Health  

Authorized signatories include:  
    Audrey French, MD, IRB Chair  
    Betty Donoval, JD, MS, Interim Director Research Regulatory Affairs  
    Audrean LaGrone, BA, IRB Manager  
    Stacey Kincaid, MPH, Informed Consent Coordinator  

The IRB follows 45 CFR 46, and IRB regulations contained in 21 CFR 50, 21 CFR 56, 45 CFR 160, and sub parts A and E of 45 CFR 164. The IRB also follows 21 CFR 11 for electronic records and signatures as part of IRBManager. The IRB is the privacy officer for human subject research and reviews for HIPAA compliance. The IRB is also largely ICH/GCP compliant within the limitations of the sponsor’s compliance. The affiliation of every IRB member is noted on the roster.

Any questions should be directed to Betty Donoval, JD, MS at bdonoval@cookcountyhhs.org or (312) 864-4821.